

## REMARKS

Applicants appreciate the thorough examination of the present application as evidenced by the Office Action dated January 25, 2006 (hereinafter, "Office Action").

Applicants appreciate the Examiner's indication that the rejections of Claims 1-19 and 21-23 under 35 U.S.C. §112, first paragraph, as lacking enablement and written description, are withdrawn. Applicants also appreciate the indication that the rejection of Claims 1-19, 21 and 22 under 35 U.S.C. §102(e) as being anticipated is withdrawn. Applicants further appreciate the indication that the rejection of Claims 2-6 under 35 U.S.C. §103(a) is withdrawn.

Claims 1-3, 6-19, 23 and 25-28 are pending in the present application upon entry of the present Amendment, and Claims 1-3, 6-19, 23 and 25-27 stand rejected. Applicants respectfully submit that Claims 1-3, 6-19, 23 and 25-28 are patentable for at least the reasons set forth below.

### **I. Claim Rejections Under 35 U.S.C. § 103**

Claims 1, 7-19, 21-23 and 24-27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 96/05846 to Nebe (hereinafter, "Nebe"), U.S. Patent No. 5,696,236 to Omar et al. (hereinafter, "Omar et al.") and EP 0798003A2 to Savage et al. (hereinafter, "Savage et al.") for reasons of record. *See* Office Action, page 3.

The Office Action states that "Applicants' argument is that the instant claims require that there is 'no detectable prion protein in the filtrate after filtration.'" This argument is not persuasive because the dependent claims (claims 21 and 22) only require that the removal must be at least  $10^3$  or  $10^4$ , this limitation is imputed onto claim 1 which is supposed to be broader than the dependent claim." Office Action, page 3. Applicants have canceled Claims 21 and 22.

The Office Action further states that "[i]t would have been obvious to one of ordinary skill in the art to utilize a depth filter, which are ordinarily used in the art as a prefilter for ultramembrane filtration . . . . The claims as written are not limited to the use of only one type of filter." Office Action, page 4. Applicants have amended Claim 1 to include the transitional phrase "consists essentially of," and Claims 17, 18 and 26 to include the transitional phrase "consisting essentially of."

In view of the amendments to the claims as discussed above, Applicants respectfully submit that Claims 1, 7-19, 23 and 25-27 are not obvious in view of the cited references, and Applicants request that the rejection of these claims be withdrawn.

## **II. Claim Rejections Under 35 U.S.C. § 102**

Claims 1, 8, 9, 14, 16-18, 21, 24, 26 and 27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Nebe. *See* Office Action, page 5. More specifically, the Office Action states that the following:

The instant invention is drawn to a method comprising the use of a depth filter (a prefilter) for the purpose of removing infectious prion protein from a solution. The claims as written are not limited to the use of only one type of filter the method steps 'comprise' the use of a depth filter, which is known in the art to be a prefilter, the claims can include other filtration steps to achieve the purpose of removing the prion protein from the sample.

Office Action, page 5.

The Office Action further states that Nebe "disclose the removal of prion from solution utilizing a series of membrane or ultramembrane filters. . . . Nebe anticipates the instant invention." Office Action, page 6.

As noted above, Applicants have amended Claims 1, 17, 18 and 26 to recite the transitional phrase "consists essentially of" or "consisting essentially of." Additional steps or materials attributed to the cited art are excluded by the recitations "consists essentially of" or "consisting essentially of." For example, inclusion of additional steps, *e.g.*, a series of filtration steps, would materially change the characteristics of Applicants' invention, which renders a product subjected to the claimed method non-infective with respect to prion protein infectivity without the need for additional steps and/or materials referenced in the cited art.

Accordingly, at least in view of the foregoing, Applicants respectfully submit that Claims 1, 8, 9, 14, 16-18, 26 and 27 are not anticipated by the cited reference, and Applicants request that the rejection of these claims be withdrawn

### **III. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph**

Claims 1-19 and 21-27 stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. *See* Office Action, page 7. More specifically, the Office Action states that "[t]he specification, while being enabling for KS80 depth filter, does not reasonably provide enablement for the use of any depth filter under any condition to remove prion protein from a sample source." Office Action, page 7. The Office Action further states that the "[t]he reference cited by applicants Reichel et al. (Vox Sanguinis, 2002) indicates that the instant invention of removing prion protein from the sample works with the KS80 filter only when there is ethanol in the sample." Office Action, page 7.

Applicants have amended Claims 1, 17, 18, 26 and 27 to recite the materials included in the KS80 filter, namely, kieselguhr or perlite particles or mixtures thereof. Regarding the significance of the presence of ethanol, however, Applicants respectfully submit that ethanol is not necessary to effectuate prion removal as recited in the claims of the present invention. Instead, Applicants submit that there has been no correlation between the presence of alcohol and the efficiency of removing infectious prion proteins. Further, the "test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." (M.P.E.P. §2164.01, citing *In re Wands*, 858 F.2d 731, 737). Applicants respectfully submit that the specification provides substantial guidance as to how the invention may be carried out with respect to the specific filter to be employed coupled with well-known biochemical techniques. As noted in the Office Action, not all depth filters are able to remove the prion protein so that the liquid is made non-infective. *See* Office Action, page 8. However, Applicants have shown that the filters in the recited claims are able to remove abnormal infective prion proteins, which may be present in the liquid such that the liquid is non-infective with respect to prion protein infectivity.

The issue is not whether some experimentation is necessary to optimize the invention; the relevant question is whether the amount of experimentation is "undue." In view of the claim amendments and remarks set forth above, Applicants respectfully submit that one skilled in the art relevant to the present invention would be able to practice the presently-claimed invention without "undue" experimentation.

Accordingly, Applicants respectfully submit that Claims 1-19, 23 and 25-27 are enabled, and Applicants request that the rejection under U.S.C. §112, first paragraph, as lacking enablement, be withdrawn.

**IV. New Claim 28**

Applicants have added new dependent Claim 28. Support for this claim can be found in the specification as originally filed, for example, page 10, Example 1, among other places. Applicants respectfully submit that new Claim 28 is patentable at least per the patentability of Claim 1. Moreover, Claim 28 is separately patentable.

**Conclusion**

Applicants respectfully submit that, for at least the reasons discussed above, the rejections of the claims have been addressed. Accordingly, Applicants respectfully request allowance of all the pending claims and passing this application to issue.

Any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



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Susan E. Freedman  
Date of Signature: April 24, 2006